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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,420	04/05/2001	James E. McGowan, JR.	1489.1001	5040

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EXAMINER

CHORBAJI, MONZER R

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 12/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/826,420

Applicant(s)

MCGOWAN, JAMES E.

Examiner

MONZER R CHORBAJI

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

This final office action is in response to the amendment received on 10/09/2003

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 15-18 and 22-29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 09/826,418. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The concepts of claims 15 and 22 of Application No. 09/826,420 are found in claims 1-2 and 9-8 of copending Application 09/826,418. The concepts are encompassed by claims 1-2 and 9-8 of copending Application 09/826,418 such that one of ordinary skill in the art cannot practice one method without practicing the other.

The concepts of claims 16-18 and 23 of Application No. 09/826,420 are found in claims 8 and 17 of copending Application 09/826,418.

The concepts of claims 24-27 of Application No. 09/826,420 are found in claims 4-7 respectively of copending Application 09/826,418.

The concepts of claims 28-29 of Application No. 09/826,420 are found in claims 1 and 11 of copending Application 09/826,418.

3. Claims 19-21 and 30-32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 09/826,418 in view of McGowan, Jr (U.S.P.N. 5,749,203).

This is a provisional obviousness-type double patenting rejection.

With respect to claims 19-21 and 30-32 of Application No. 09/826,420, the claims of copending Application No. 09/826,418 fail to teach the following: substantially no moisture is supplied to the medical article at the sterilization-sealing station, evacuating the housing at the sterilization-sealing station so as to remove moisture from the medical article, maintaining the pressure in the housing so as to allow some moisture to remain with the medical article, and maintaining the pressure in the housing so as to allow the relative humidity in the housing to be at least 40% during sterilization gas exposure. However, with respect to claims 19 and 30 of Application No. 09/826,420, claims 2, 8, and 11 of copending Application No. 09/826,418 disclose the following concepts: sterilization and sealing are conducted at a sterilization-sealing station and steam is supplied to the medical article at the pretreatment area. With respect to claims 19-21 and 30-32, McGowan, Jr. teaches that following is known: substantially no

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moisture is supplied to the medical article at the sterilization-sealing station (col.2, lines 42-58), evacuating the housing at the sterilization-sealing station so as to remove moisture from the medical article (col.2, lines 48-50) such that the evacuation step maintains the pressure in the housing within a range to inherently allow some moisture to remain with the medical article (col.2, lines 48-52), and maintaining the pressure in the housing so as to allow the relative humidity in the housing to be at least 40% during sterilization gas exposure (col.1, lines 57-65). Thus, it would have been obvious to one having ordinary skill in the art to modify the claims of copending Application 09/826,418 by utilizing the teachings of McGowan, Jr. in order to assure the moistening of all the articles within the sealed sterilization chamber (McGowan, Jr., col.1, lines 60-62).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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6. Claims 1, 4-7, 15, and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGowan, Jr. (U.S.P.N. 5,749,203).

With respect to claims 1 and 15, McGowan, Jr. discloses a device (figure 1, 10) and a method (col.1, lines 5-9) for article sterilization such that a pretreatment area for heating medical articles is known (col.1, lines 28-34). Further, McGowan, Jr. teaches the following: a device to form a housing in a first web (col.3, lines 27-29), an article loading station (col.3, lines 25-27), an alignment device (col.3, lines 38-42), a sterilization-sealing station for sterilizing a medical article inside the housing (col.3, lines 53-55), and sealing the medical article within the housing (col.4, lines 5-9).

With respect to claims 4-5 and 19, McGowan, Jr. discloses the following: the sterilization-sealing station includes a steam source (col.3, lines 38-46), substantially no moisture is supplied to the medical articles at the sterilization-sealing station (col.2, lines 42-58), and the pretreatment area has a steam supply (col.1, lines 28-33).

With respect to claims 6-7 and 20-21, McGowan, Jr. discloses the following: the sterilization-sealing station includes a vacuum (col.1, lines 50-53) and a controller such that a controller is inherent to maintain the pressure in the housing (col.1, lines 52-53). In addition, a controller is inherent to maintaining the pressure in the housing as to allow the relative humidity to be at least 40% during sterilization gas exposure (col.2, lines 57-67).

With respect to claim 18, McGowan, Jr. discloses injecting steam into the housing (col.10, lines 61-64).

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7. Claims 2-3, 8-14, 16-17, and 22-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGowan, Jr. (U.S.P.N. 5,749,203) and further in view of Multivac Packing Machines (IDS).

With respect to claims 2, 8, 16-17, and 22-23, McGowan, Jr. discloses a device (figure 1, 10) and a method (col.1, lines 5-9) for article sterilization including the following: a device to form a housing in the first web (col.3, lines 27-29), an article loading station (col.3, lines 25-27), an alignment device (col.3, lines 38-42), a sterilization-sealing station where the article is sterilized by injecting gas between the first and second webs using injection nozzles (figure 4D), and then sealing the housing (col.4, lines 5-9). However, McGowan, Jr fails to teach injecting gas by using pins. The disclosure of the Multivac Packing Machines teaches injection by using pins (advantages column). Thus, it would have been obvious to one having ordinary skill in the art to modify McGowan, Jr method and device to include gas injection pins in order to establish uniformity of gas distribution (advantages column, lines 11-12).

With respect to claims 3, 9, and 24, McGowan, Jr. teaches injecting steam into the housing between the first and second webs (figure 4D and col.10, lines 52-53) and the injected steam pressurizes the housing to a pressure of 60 to 100 Psia (col.10, lines 54-55).

With respect to claims 10 and 29, McGowan, Jr. discloses that it is known to have a pretreatment area for heating the medical articles (col.1, lines 28-33).

With respect to claims 11 and 28, McGowan, Jr. teaches that both the bottom and the top webs are formed of a gas permeable material (col.3, lines 29-31).

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With respect to claim 12, McGowan, Jr. teaches the following: substantially no moisture is supplied to the medical articles at the sterilization-sealing station (col.2, lines 42-58) and the pretreatment area has a steam supply (col.1, lines 28-33) to supply moisture to the medical articles.

With respect to claims 13-14, McGowan, Jr. discloses the following: the sterilization-sealing station includes a vacuum (col.1, lines 50-53) and a controller such that a controller is inherent to maintain the pressure in the housing (col.1, lines 52-53). In addition, a controller is inherent to maintaining the pressure in the housing as to allow the relative humidity to be at least 40% during sterilization gas exposure (col.2, lines 57-67).

With respect to claim 25, McGowan, Jr. teaches evacuating the housing before pressurizing with steam (figure 4C). With respect to evacuating the housing after pressurizing with steam, McGowan teaches that after removing the supply of steam then the sterilizing gas is introduced (col.10, lines 64-65). However, since the housing is not sealed yet; removing the supply of steam would inherently result in steam moving out of the housing and in reducing the pressure within the housing.

With respect to claim 26, even though McGowan, Jr. does not explicitly teach of a time period of maintaining the housing with steam, certainly some time interval is needed to reach the specified steam pressure within the housing (col.10, lines 62-64).

With respect to claim 27, McGowan, Jr. teaches pressurizing the housing with

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steam and with sterilizing gas within a form, fill and seal device (10) having sterilization–sealing station (410). With regard to the Btu values, even though McGowan does not explicitly disclose such values, however, McGowan pressurizes the housing with steam to a pressure of 80 Psia such that McGowan is delivering energy that falls within the Btu value range.

With respect to claims 30-32, McGowan, Jr. discloses the following: sterilization and sealing are conducted at a sterilization-sealing station (col.2, lines 42-58), the sterilization-sealing station includes a steam source (col.3, lines 38-46), substantially no moisture is supplied to the medical articles at the sterilization-sealing station (col.2, lines 42-58), the pretreatment area has a steam supply (col.1, lines 28-33), the sterilization-sealing station includes a vacuum (col.1, lines 50-53), maintaining the pressure in the housing (col.1, lines 52-53), and maintaining the pressure in the housing as to allow the relative humidity to be at least 40% during sterilization gas exposure (col.2, lines 57-67).

Response to Arguments

8. Applicant's arguments filed 10/09/2003 have been fully considered but they are not persuasive.

On page 8 of the response, applicant argues, "Although the '203 patent recognizes preheating, the paragraph bridging columns 2 and 3 indicates that one drawback associated with the related art process is the length of time required for the process". With Regard to choosing the length of time such a concept is a subjective matter depending on the choice of the artisan. In addition, the teaching of preheating is a part of the '203 reference, which is available to one skilled in the art to choose from.

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Thus, any part of a reference is a teaching that can be applied against any limitations in the claims.

On page 8 of the response, applicant argues, "Nowhere does the '203 patent suggest that preheating may be used with the form-fill-and-seal machine". Form-fill-and-seal concept is mentioned in columns 1-2 where reusable surgical articles and placed in containers then later sealed. For example, see col.2, lines 31-65. Even though, it is not explicitly called form-fill-and-seal process, it still involves forming a container, filling the container with a surgical article, then sterilizing and sealing the article. Please note that any reference is taken as a whole and any part of it constitutes a teaching.

On page 9 of the response, applicant argues, "Throughout the '203 patent it is described that sterilization occurs after the first and second webs are sealed". In the '203 patent in col.2, lines 35-36 and lines 52-55, the articles are sterilized and then sealed.

On page 9 of the response, applicant argues, "the '203 patent contains numerous tables which show that sterility does not occur until after sufficient degassing". None of the claims teach achieving instantaneous sterilization of the articles. Furthermore, the specification and the '203 reference teach the same steps in sterilizing articles. Then, how can it be concluded that the '203 reference is not achieving instantaneous sterilization while the specification for this application is achieving instantaneous sterilization of articles. Thus, it is believed that both are achieving instantaneous sterilization of articles.

On page 10 of the response, applicant argues, "the Multivac Packaging

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Machines reference does not suggest sealing the first web to the second web after sterilizing the medical article". The Multivac Packaging Machines reference is used for only one reason, which is injecting gas by using pins and not for sealing the webs after sterilizing the medical article.

Conclusion

9. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

10. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 8:30-5:00.

12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (571) 272-1281. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

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872-9310 for regular communications and (703) 872-9311 for After Final communications.

13. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Monzer R. Chorbaji *MRC*
Patent Examiner
AU 1744

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